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09/929,862	08/14/2001	Charles L. Shear	PC11025AADO	9844

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Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER	
HENLEY III, RAYMOND J	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/929,862
Filing Date: August 14, 2001
Appellants: SHEAR, CHARLES L.

A. Dean Olson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 12, 2005 appealing from the Office action mailed June 22, 2005

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

Neither the Examiner nor the Appellant is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct with the exception of the last line thereof with refers to the merits of the present invention, i.e., "Appellant discovered that the CETP inhibitor compound and atorvastatin hydroxy metabolite, if used together in combination with a carrier, vehicle or diluent, *provide a significant medical benefit.*"(emphasis added).

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 00/17164	DENINNO et al.	3-2000
4,681,893	ROTH	7-1987

(9) Grounds of Rejection

The following ground of rejection are applicable to the appealed claims:

Claims 1, 4, 5 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deninno et al. (WO 00/17164) in view of Roth (U.S. Patent No. 4,681,893).

Deninno et al. teach methods and compositions for treating atherosclerosis, dyslipidemia, hypertriglyceridemia, hypercholesterolemia, cardiovascular disorders and angina (see page 22,

lines 25-28) through the administration of a composition which may comprise [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-l-carboxylic acid ethyl ester (see page 9, lines 25-26) and a second compound which may be preferably an HMG-CoA reductase inhibitor (page 30, line 14) and which further may be particularly preferably being selected from a group of such reductase inhibitors which includes atorvastatin (page 30, line 16).

The difference between the above and the claimed subject matter lies in that Deninno et al. only highlights atorvastatin and fails to teach the presently claimed salts and/or hydroxy acid forms thereof (see, for example, claims of formula I and IA in Appellant's claim 1).

However, the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Roth teaches the presently claimed salt forms and hydroxy acid forms of atorvastatin (see the abstract, column 2, lines 3-43 and colunm 7, lines 1-17) as being efective HMG-CoA reductase inhibitors and the skilled artisan would have been motivated to alternatively use these compounds of Roth for the purpose taught by Dennino et al. for atorvastatin because not only was it known that atorvastatin (see Deninno et al. as referenced above) and the presently claimed salt forms and hydroxy acid forms of atorvastatin were known to function as HMG-CoA reductase inhibitors (see Roth as referenced above), but Dennino et al. teach that HMG-CoA reductase inhibitors in general could be combined with [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-l-carboxylic acid ethyl ester for the purposes taught therein and presently claimed.

(10) Response to Argument

Appellant's arguments at pages 5-12 of their brief have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Throughout pages 5-12, Appellant has relied on *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987), which addresses what must be considered when concluding that it would have been obvious to combine two active agents, each known individually for the same purposes. Appellants contend that from the teachings of the references relied on by the Examiner, no motivation to combine the CETP inhibitor [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-l-carboxylic acid ethyl ester and the presently claimed salt forms and hydroxy acid forms of atorvastatin exists and that, at best, it would have only have been "obvious to try" such a combination. However, it is believed that the Examiner has fully met all of the applicable standards in determining that it would have been obvious to do what Appellants have done.

As stated in the MPEP § 2145(X)(B), "'The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.... In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.' *In re O 'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673,

1681 (Fed. Cir. 1988)". Here, as noted above, Dennino et al. clearly identifies that HMG-CoA reductase inhibitors should be used with the claimed CETP inhibitor [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-l-carboxylic acid ethyl ester. This fact has not been denied by Appellant. Therefore, the selection of any HMG-CoA reductase inhibitor would have been within the purview of the skilled artisan. Further, because the present claims combine atorvastatin analogs with the CETP inhibitor and atorvastatin is identified in the art as a preferable HMG-CoA reductase inhibitor, a conclusion of obviousness is even more difficult to avoid.

Appellant at pages 9-12 of the brief has further identified other Court decisions which they believe to compel the Examiner to find that the claimed subject matter would not have been obvious, but rather would have bee merely "obvious to try". The Examiner is not persuaded by such statements. That is, the Examiner has pointed to page and line in the references to show what the references teach; has identified the differences between the teachings of the references; and has identified the motivation that would have imbued the skill artisan to do what Appellants have done with a reasonable expectation of success. Appellant, on the other hand, has not factually disputed any of the Examiner's findings. The facts set forth in the references relied on compel a conclusion of obviousness.

For the above reasons, it is respectfully submitted that the rejection should be sustained.

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferee

Conferee

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Raymond J. Henley III

RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614